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**EXAMINER** 

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10/03/2003

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10/678,805

ART UNIT PAPER NUMBER

3256

1637

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101 Howard Street San Francisco, CA 94105

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Commence	10/678,805	KRISHNAN ET AL.
Office Action Summary	Examiner	Art Unit
	Cynthia B. Wilder, Ph.D.	1637
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on 13 April 2006.		
	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 455 C.G. 215.		
Disposition of Claims		
4)⊠ Claim(s) <u>1-15,17-25 and 27-31</u> is/are pending in the application.		
4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.		
5)⊠ Claim(s) <u>22-25, 27-31</u> is/are allowed.		
6)⊠ Claim(s) 1-8,14,15 and 17-21 is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) ⊠ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summary Paper No(s)/Mail Da	
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)		Patent Application (PTO-152)
Paper No(s)/Mail Date	6)	

### **DETAILED ACTION**

1. Applicant's amendment filed 4/13/2006 is acknowledged and has been entered. Claim 1 has been amended. Claims 1, 7, 14, 17, 20, 22, 26, 27, 30 have been amended. Claim 16 has been canceled. Claims 1-15 and 17-25, 27-31 are pending. Claims 9-13 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-8, 14, 15 and 17-31 are addressed in this Office Action. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections necessitated by Applicant's amendment of the claims. Any rejection not reiterated in this action has been

#### This action is made FINAL.

withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Previous Rejections

3. The prior art rejections under 35 USC 102 are withdrawn in view of Applicant's amendment of the claims. The claim rejections under 35 USC 112 second paragraph are withdrawn in view of Applicant's amendment of the claims.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

# Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 3 is indefinite because it appears to be redundant to claim 1 as currently amended and does not further limit the subject matter therein. Clarification is required.

### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 14, 15 and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sogard et al (US 2003/0077599). Regarding claims 1 and 14, Sogard et al teach a method, comprising providing a reaction vessel comprising a top and a bottom, a heat source contacting said bottom of said reaction vessel, an active cooling means contacting said top of said reaction vessel, wherein said cooling means comprises a water bath and solution comprising a plurality of reactants; introducing said solution into said reaction vessel; and creating a convection cell<sup>1</sup> by

Wikipedia encyclopedia defines a convection cell as a phenomenon of fluid dynamics which occurs in situations where there are temperature differences within a body of liquid or gas.

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applying heat to said bottom of said vessel with said heat source and cooling said top of said vessel with said cooling means under such conditions that said reactants form a reaction product (Figure 1; Figure 3; 0013-0014; 0040-0044; and 0049-0050).

Regarding claims 2-4, 15 and 17, Sogard et al teach the method of claims 1 and 14 as previously described above. Sogard et al teach that the method and device can be used in hybridization and binding assays and may comprise amplified nucleic acids, via PCR techniques (0056-0057). Therefore, a nucleic acid comprising a target and primer substantially homologous to a least a portion of said target are inherent in the teaching of the nucleic acid amplification reaction via PCR.

Regarding claims 5 and 18, Sogard et al teach the method of claims 1 and 14, wherein said reaction vessel comprises at least functionalized glass (0065, Figure 1).

Regarding claim 6 and 19, Sogard et al teach the method of claims 1 and 14, wherein said reaction vessel is part of an array (0065, Figure 1).

Regarding claim 7 and 20, Sogard et al teach the method of claims 1 and 14, wherein a temperature gradient of between about 5 degrees Celsius and 25 degrees Celsius or more preferably about 10 degrees Celsius/mm is used (0047).

Regarding claim 8 and 21, Sogard et al teach the method of claims 1 and 14, also providing an input tube connected to a inlet port or fluidic interface port, which is in fluid communication with said reaction vessel (0053 and Figure 1). Therefore, Sogard et al meets the limitations of claims 1-8, 14, 15 and 17-21 of the instant invention.

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## Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the

manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 14, 15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over

in view of Ecke et al (International Journal of Engineering Science, vol. 36, pages 1471-1480,

1998) in view of Vorobieff et al (Physica D, vol. 123, pages 153-160, 1998), and further in view

of Selvaganapathy et al (Proceedings of the IEEE, vol. 91, no. 6, June 2003). Regarding claims

1-4, 14, 15, 17, Ecke et al teach a reaction vessel and method, as disclosed by Vorobieff et al

(page 154-155, section entitled "experimental setup and data acquisition system), said reaction

vessel comprising a top and a bottom, a heat source, contacting said bottom of said reaction

vessel and an active cooling means contacting said top of said reaction vessel, wherein said

cooling means is selected as a cooling bath a and solution; introducing said solution into said

vessel and creating at least one convection cell by applying heat to said bottom of said vessel

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with said hear source and cooling said top of said vessel with said cooling means under appropriate conditions (page 1473, section entitled "2 Experiment").

Ecke et al in view of Vorobieff do not teach wherein the solution introduced into the reaction vessel comprises a plurality of reactants, wherein said reactants comprise nucleic acid comprising and primers substantially homologous to at least a portion of said target.

Selvaganapathy et al provides a review article on the recent progress in microfluidic devices for nucleic acid assays, including PCR microdevices for use in amplification of nucleic acid molecules. Selvaganapathy et al teach that the use of naturally developed Raleigh-Benard convection between two regions of differing temperature may be used for performing PCR (page 955, second column, bottom of first full paragraph). Selvaganaphy teach that the amplification reaction will comprises the use of reactants such a nucleic acid comprising a target and primer substantially homologu to a least a portion of said target. Additionally, Selvaganapathy et al teach wherein the amplified products are formed (page 954-955, section entitled "Amplification Chips").

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention that a solution comprising a plurality of reactants, such as nucleic acid targets and primers, can be applied to the reaction vessel and method as taught by Ecke et al in view of Vorobieff et al with a reasonable expectation of success based on the teachings of Selvaganapathy et al that the use of naturally developed Raleigh-Benard convection between two regions of differing temperature may be used for performing PCR amplification procedures.

Regarding claim 5, 18, Ecke et al teach wherein the reaction vessel comprises material comprising PLEXIGLASS and silicones (page 1473, section entitled "Experiment").

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#### Conclusion

8. Claims 1-8 and 14, 15, 17-21 are not allowed. Claims 22-25 and 27-31 have not been rejected under prior art because no prior art was found teaching a method and reaction vessel as described in the claim 22, wherein the reaction vessel is configured with an aspect ratio of at least 3.3. The closest prior art, Vorobieff (citation noted above) teach a reaction vessel as described above configured with an aspect ratio of about 2. Vorobieff et al also do not teach wherein the reaction vessel is contacted with a solution comprising a plurality of reactants as claimed therein or the use of the reaction vessel with nucleic acid molecules.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail.

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Alternatively, a request for a return telephone call may be emailed to <u>cynthia.wilder@uspto.gov</u>. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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